Draft Project Description **8/22/01**

Assignment Title: Impact of Science on Rule-Making: Phase I (Feasibility and Design)

Description: Administrator Whitman chose as one of EPA's three budget priorities in FY 2002, "to improve the role of science in decision-making by having scientific information and analysis help in directing policy and establishing priorities." EPA's Inspector General is considering whether to undertake an evaluation of the characteristics of science/research that is most 'useful' in EPA's primary rule making. The purpose of the project would be to identify the funding sources, funding mechanism, institution type where the research is conducted, publication outlet and peer review process of the science that proved most useful, historically, in the rule-making process, in order to promote more useful science.

As a special project, the OIG will begin the scoping and design phase of a longer-term project in August, 2001. Currently, we assume that the project will focus on major rules (reportable under EO 12866) that have become final over the last 10 years. The scoping and design phase will be restricted to developing the variables that would be most useful in providing information to meet the objectives, the availability of that information, and the development of a reliable sampling design to collect the information for the evaluation. Based on the results of Phase I, a determination of the feasibility and cost-effectiveness of the evaluation will be made. During Phase I project personnel will consult with organizations who have previously done case studies on the use of science in decision-making at EPA, scientists and decision-makers in EPA's programs and regions, stakeholders in the rule-making process, and EPA's Science Advisory Board for their views on the most important variables for the study.

Assignment Objectives:

The objectives of the scoping and design phase (Phase I) include:

- Identify the types of rules that will be included in the study
- Develop a sampling frame (lists of rules from which the statistical samples will be drawn) and a sampling design (how the sample will be drawn from the frame; sample size, stratification, etc.) if the number of rules is too large to be evaluated in it's entirety
- Identify the measures to be made of the characteristics of the critical science supporting each rule (e.g., funding source, funding vehicle, type of organization conducting the research, period over which the research was conducted, where published, nature of peer review, etc.).
- Determine whether characteristics can be measured of the scientific "quality" of the rule (e.g., rapid adoption by the States or regulated community, withstands court challenges, etc.) that could be related to the characteristics of the science inputs.
- Conduct a pilot survey to determine whether the data on these measures are available and can be gathered efficiently and effectively by OIG audit staff.
- Estimate the level of effort, resources, and time needed to complete the full study

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Draft Decision Rules for Identifying Respondents **8/22/01**

- Regulatory team leader (Program Office)
- Science Lead (ORD)
- Science Lead (Program Office)
- Cognizant Division or Office Director (SES level)
- Peer Review Lead (SAB? Other?)
- Evaluator (based on reading of the rule)?

Draft Questions on Science Inputs to Major EPA rules 8/22/01

(The intention would be to reduce most answers to categorical variables)

At the beginning of the rule-making process, what were the five most important science findings that influenced the rule? For each one:

- Who funded the work?
- What funding mechanism (grant, contract, IAG, in-house?
- Who performed the work?
- Where/how was it published?
- What was the nature of the peer review?

As rule-making progressed, what were the five most important research projects undertaken to support the rule? For each one:

- Who funded the work?
- What funding mechanism (grant, contract, IAG, in-house) was used?
- Who performed the work?
- Where/how was it published?
- What was the nature of the peer review

Was there an important modeling component to support the rule-making? If so:

- Who funded the development of the model?
- What funding mechanism (grant, contract, IAG, in-house) was used?
- Who performed the work?
- Where/how was the final model published?
- What was the nature of the per review of the model?
- Who funded the model runs to support the rule?
- What funding mechanism (grant, contract, IAG, in-house) was used?
- Who performed the model runs?
- Where/how were the model runs published?
- What was the nature of the peer review?

Does the rule specify a monitoring or methodology? If so:

- Who funded the development of the method?
- What funding mechanism (grant, contract, IAG, in-house) was used?
- Who performed the work?
- Where/how was it published?
- What was the nature of the peer review?

What were the critical data sets used to support the rule?

- Who funded the development of the data set?
- What funding mechanism (grant, contract, IAG, in-house) was used?
- Who collected the data?
- What was the nature of the QA review?

Draft Questions on Science Inputs to Major EPA rules (continued) 8/22/01

For the rule-making process itself:

- Who were the five most important people in the process? Who did they work for?
- When did planning for the science behind the rule start?
- What was the total resource input to the rule?
- What were the total S&T expenditures on the issue (regardless of whether they influenced the rule)**?**

What was the nature of scientific revue of the rule?

- Who were the reviewers?
- Any COI among the reviewers?
- What were the responses to any substantive findings?

What was the scientific burden of proof required by the relevant statute?

Draft Questions on "Quality" of Major EPA Rules 8/22/01

What was the estimated economic cost of the rule? What was the breadth of impact (e.g., all municipalities, a few manufacturers, the motoring public)?

How long did it take to finalize the rule?

How much was the proposed rule revised as a result of scientific peer review or technical comments?

To what extent was the rule criticized on technical merits in the press?

Was the proposed rule withdrawn or subsequently modified?

Was the rule overturned on technical merits by the courts?